

§ 186.1771

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging and as a component of lubricants with incidental food contact in accordance with § 178.3570 of this chapter, with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1771 Sodium palmitate.

(a) Sodium palmitate ($C_{16}H_{31}O_2Na$, CAS Reg. No. 408-35-5) is the sodium salt of palmitic acid (hexadecanoic acid). It exists as a white to yellow powder. Commercially, sodium palmitate is made by mixing and heating flaked sodium hydroxide and palmitic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na_2SO_4 , CAS Reg. No. 7757-82-6), also known as Glauber's salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980]

§ 186.1839 Sorbose.

(a) Sorbose (L-sorbose, sorbinose) ($C_6H_{12}O_6$, CAS Reg. No. 87-79-6) is an

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orthorhombic, bisphenoidal crystalline ketohexose. It was originally identified in the juice of mature berries from the mountain ash (*Sorbus aucuparia*) where it occurs as the result of microbial oxidation of sorbitol. It also occurs naturally in other plants. Sorbose can be synthesized by the catalytic hydrogenation of glucose to D-sorbitol. The resulting sorbitol can be oxidized by *Acetobacter xylinum* or by *Acetobacter suboxydans*.

(b) The ingredient is used or intended for indirect food use as a constituent of cotton, cotton fabrics, paper, and paperboard in contact with dry food.

(c) The ingredient migrates to food at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11698, Mar. 21, 1978, as amended at 48 FR 48457, Oct. 19, 1983]

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

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AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14659, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 189 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to part 10 of this chapter, and will be published for comment if it contains reasonable grounds.

[42 FR 14659, Mar. 15, 1977, as amended at 54 FR 24899, June 12, 1989]

Subpart B—Prohibited Cattle Materials

§ 189.5 Prohibited cattle materials.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials* means specified risk materials, small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed, or MS(Beef). Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically Separated (MS)(Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions.

(5) *Specified risk material* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete